

REMARKS/ARGUMENTS

This paper is responsive to the Office Action mailed October 20, 2009. Claims 1-8, 10-16, 18-24, 33-40 and 55-73 were pending before submission of this paper. Claims 1-8, 10-16, 18-24, 33-40, and 55-73 stand rejected. Specifically, claims 1, 8, 10-16, 18-24, 33-36, 38-40 and 59 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler et al. (US 6,129,756), Elliot (US 2003/0236567), Greenberg (US 2004/0193254), Vrba (US 6,168,621) and Austin (US 6,945,994). Applicants respectfully disagree. Claims 1, 33, and 64-65 have been amended. Claims 74-84 are new. Support for all amended claims can be found in the specification, and no new matter has been added by these amendments. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

I. Claims 1, 10-16, 18-24, 33-36 and 38-40 Are Allowable Under 35 U.S.C. § 103 Over Kugler in View of Elliot and Greenberg

Claims 2-7, 37, 55-58 and 60-73 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler in view of Elliot and Greenberg in further view of Vrba.

With regard to rejections under 35 U.S.C. § 103, the Examiner must provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not. M.P.E.P. § 2142. Accordingly, “the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” M.P.E.P. § 2142; *see KSR International Co. v. Teleflex, Inc.*, 550 U.S.398, 82 USPQ 2d 1385, 1395-97 (2007).

A. Independent Claim 1

Applicants’ claim 1, as amended, recites:

1. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:

at least one stent member comprising at least one of a self-expanding stent member and a balloon-expandable stent member;

at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, said at least one tubular graft member, once deployed, comprising a main graft member toward the proximal end of the tubular graft member and at least one sinusoidal leg member, each of said at least one sinusoidal leg member being coupled with the main graft member at its proximal end and extending toward the distal end of the tubular graft member and said at least one sinusoidal leg member having shape memory biasing said at least one sinusoidal leg member toward a sinusoidal shape; and

at least one skirt graft member coupled with at least one of the stent member and the tubular graft member at or near the proximal end of the tubular graft member and extending toward the distal end,

wherein the skirt graft member is configured to be placed in contact with the inner wall of the aortic aneurysm when the stent-graft device is implanted adjacent to the abdominal aortic aneurysm.

Such subject matter as recited in claim 1 is not disclosed, taught, or suggested by the proposed combination of Kugler, Elliot, and Greenberg.

For example, claim 1 recites “at least one sinusoidal leg member” that has “shape memory biasing said at least one sinusoidal leg member toward a sinusoidal shape.” The Office Action at pages 3-4 expressly acknowledges that Kugler does not teach a sinusoidal leg member as recited in claim 1, but alleges that sinusoidal leg members are well known in the art and cites to Greenberg’s Figures 8a-8d as an example. (Presumably, the Office Action refers to Greenberg’s “prosthetic branch 144” described in paragraph 99.)

Applicants submit that, even assuming *arguendo* that Greenberg teaches a sinusoidal leg member, the reference still would not teach a sinusoidal leg member that includes shape memory that biases the sinusoidal leg member toward a sinusoidal shape, as recited in claim 1. For instance, Greenberg does not describe that the prosthetic branch 144 includes shape memory that biases the branch to a particular shape. In fact, Greenberg in paragraph 99 merely describes that “the prosthetic branch 144 is preferably made of woven, crimped polyester” but is silent regarding any type of shape memory characteristics.

In addition to the foregoing, Applicants respectfully disagree with the Office Action’s assertion on page 4 that providing a sinusoidal leg member is merely changing the

shape of a working part involving only routine skill in the art pursuant to *In re Dailey*, 357 F.2d 669, 149, U.S.P.Q. 47 (C.C.P.A. 1966). In particular, Applicants respectfully reiterate the reasons outlined in their August 14, 2009 response—which are not addressed in the present Office Action—why the holding of *Dailey* is inapplicable to the present claims. Also, Applicants respectfully point out that the secondary reference Elliot, which is cited for a skirt by the Office Action on page 4, does not make up for the failure of Kugler and Greenberg to cite the “sinusoidal leg member” having “shape memory” as recited in claim 1, since the reference does not show even a sinusoidal leg member.

In light of the foregoing, Applicants respectfully submit that the proposed combination of Kugler, Elliot, and Greenberg does not disclose, teach, or even suggest all elements of claim 1. Therefore, claim 1 is allowable under 35 U.S.C. § 103 over Kugler in view of Elliot and Greenberg. Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103 be withdrawn.

B. Independent Claim 33

Applicants respectfully submit that independent claim 33 is allowable under 35 U.S.C. § 103 at least for reasons including some of those discussed above in connection with claim 1. For example, amended claim 33 recites “at least one graft member coupled with and extending between the proximal stent member and the at least one distal stent member” where “at least a portion of the graft member [is] pre-shaped with at least one bend having shape memory such that, upon deployment, said at least a portion of the graft member has is biased to have an elongatable a sinusoidal shape.” As discussed above, a graft member having “shape memory” as recited in claim 33 is not disclosed, taught, or even suggested by the proposed combination of Kugler, Elliot, and Greenberg. Therefore, Applicants respectfully request that the rejection of claim 33 under 35 U.S.C. § 103 over Kugler in view of Elliot and Greenberg be withdrawn.

C. Independent Claim 55

Claim 55 recites:

55. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:

at least one stent member comprising a plurality of expandable members coupled together circumferentially to form a cylinder, some of the expandable members comprising a self-expanding material others of the expandable members comprising a balloon-expandable material; and

at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, wherein the at least one stent member is configured to anchor the tubular graft member in an artery selected from the aorta and an iliac artery.

Such subject matter is alleged by the Office Action on pages 5-6 to be obvious under 35 U.S.C. § 103 over Kugler, in view of Elliot, Greenberg, and Vrba. Applicants respectfully disagree.

For example, as noted, claim 55 recites “at least one stent member comprising a plurality of expandable members coupled together circumferentially to form a cylinder” where “some of the expandable members [comprise] a self-expanding material others of the expandable members [comprise] a balloon-expandable material.” At least this subject matter is not disclosed, taught, or even suggested by the proposed combination of Kugler, Elliot, Greenberg, and Vrba.

As an initial matter, Applicants respectfully note that the Office Action does not address this element, and, therefore, has not made a *prima facie* case of obviousness of claim 55. Nevertheless, assuming *arguendo* that the Office Action had alleged that this element is taught by a combination of Kugler, Elliot, Greenberg, and Vrba, Applicants submit that the proposed combination of Kugler, Elliot, Greenberg, and Vrba nevertheless would not disclose, teach, or suggest at least the above element of claim 55. As acknowledged by the Office Action at page 5, the proposed combination of Kugler, Elliot, and Greenberg does not teach a stent member comprising both a self-expanding stent member and a balloon-expandable stent member. The Office Action at page 5 alleges that Vrba makes up for this deficiency. Applicants respectfully submit that, even if Vrba makes up for the failure of Kugler, Elliot, and Greenberg to teach “a stent member comprising both a self-expanding stent member and a balloon-expandable stent member,” Vrba still would not teach the configuration recited in claim 55.

As previously noted in Applicants response filed August 14, 2009, Vrba teaches self-expanding sections joined to balloon-expandable sections axially. Claim 55, on the other hand, recites “a plurality of expandable members coupled together circumferentially to form a cylinder” where “some of the expandable members [comprise] a self-expanding material others of the expandable members [comprise] a balloon-expandable material.” For reasons noted in Applicant’s August 14, 2009 response, the configuration recited in claim 55 provides advantages over the device taught in Vrba. Thus, Vrba does not, in fact, make up for the failure of Kugler, Elliot, and Greenberg to teach all elements of claim 55. Therefore, Applicants respectfully submit that claim 55 is allowable under 35 U.S.C. § 103 over Kugler in view of Elliot, Greenberg, and Vrba.

D. Independent Claim 64

As amended, claim 64 recites:

64. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:

at least one stent member comprising at least one of a self-expanding stent layer and a balloon-expandable stent layer, the self-expanding stent layer and balloon-expandable stent layer being radially laminated to one another; and

at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, wherein the at least one stent member is configured to anchor the tubular graft member in an artery selected from the aorta and an iliac artery.

Such subject matter is not taught, disclosed, or suggested by the proposed combination of Kugler, Elliot, Greenberg, and Vrba.

For example, as discussed above, the Office Action acknowledges that the proposed combination of Kugler, Elliot, and Greenberg does not teach a stent member comprising both a self-expanding stent member and a balloon-expandable stent member and, therefore, does not teach a stent member “comprising at least one of a self-expanding stent layer and a balloon-expandable stent layer,” where the layers are laminated together, as recited in claim 64.

The Office Action at pages 6-7, however, alleges that Vrba's axially-connected self-expanding and balloon-expandable sections are disclosed as laminated because its sections are "composed of layers [of] firmly united materials." Referring to Vrba's Figure 6, it can be seen that Vrba discloses a device where the self-expanding and balloon-expandable sections are disclosed as being axially connected to one another. In other words, the Office Action at pages 6-7 alleges that Vrba teaches self-expanding and balloon-expandable layers that are laminated axially. Applicants have amended claim 64 to clarify that the recited self-expanding layer and balloon-expandable layer are "radially laminated" in order to distinguish from the axially-layered sections of Vrba. Therefore, Applicants respectfully submit that the proposed combination of Kugler, Elliot, Greenberg, and Vrba does not teach all elements of claim 55 and, therefore, that claim 55 is allowable under 35 U.S.C. § 103.

E. New Independent Claims 74 and 79

Applicants respectfully submit that new claims 74 and 79 are allowable over the art of record at least for reasons including some of those discussed above. For example, claim 74 recites a stent-graft device that includes "at least one sinusoidal leg member having shape memory biasing said at least one sinusoidal leg member toward a sinusoidal shape." As discussed above, the art of record does not render at least such subject matter obvious under 35 U.S.C. § 103.

Applicant's new claim 74 recites:

- 74. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:
 - a stent member;
 - a tubular graft member coupled with the stent member, the tubular graft member having a proximal end and comprising:
 - a main graft member toward the proximal end of the tubular graft member, and
 - a first leg member and a second leg member permanently coupled with the main graft member, at least one of the first leg member and second leg member having a distal end configured to be attached with an iliac artery upon deployment; and

a skirt graft member coupled with the stent member and the tubular graft member at or near the proximal end of the tubular graft member and extending toward the distal end, the skirt graft member being configured to be placed in contact with the inner wall of the aortic aneurysm when the stent-graft device is implanted adjacent to the abdominal aortic aneurysm.

Such subject matter as recited in claim 74 is supported by the specification as filed and not disclosed, taught, or suggested by the art of record. As discussed above, the Office Action cites to Kugler, Elliot, and Greenberg in rejecting claim 1 which recites “at least one skirt graft member coupled with at least one of the stent member.” Applicants respectfully submit that, even assuming *arguendo* that the proposed combination of Kugler, Elliot, and Greenberg rendered claim 1 (prior to the present amendment) obvious under 35 U.S.C. § 103, the proposed combination of references still would not render claim 74 obvious because the proposed combination of references still would not teach all elements of claim 74.

As a specific example, claim 74 recites “a first leg member and a second leg member permanently coupled with the main graft member.” Kugler (which the Office Action cites for the stent member to which the Office Action proposes Elliot’s skirt be attached), however, does not teach leg members permanently coupled with a main graft member, but rather two-legged graft systems in which leg portions are attached *in situ*. See Kugler, Figs. 7-19. As a result, the proposed combination of Kugler, Elliot, Greenberg, and Vrba would not disclose, teach, or even suggest all elements of claim 74. Therefore, Applicants respectfully submit that claim 74 is allowable under 35 U.S.C. § 103 over Kugler, Elliot, Greenberg, and Vrba.

Claim 79 recites a stent device that includes “a plurality of expandable members coupled together to form a cylinder, the cylinder having a first end portion, a second end portion, and a middle portion between the first end portion and second end portion” and where “the expandable members [include] at least one self-expanding member and at least one balloon-expandable member... disposed in the middle portion.” The Office Action at page 6 (rejecting claim 56) acknowledges that the proposed combination of Kugler, Elliot, Greenberg, and Vrba does not teach a configuration of self-expanding and balloon-expandable members where the middle portion comprises both self-expanding members and balloon-expandable members, but alleges that such a configuration would nevertheless be obvious over the references. In

particular, the Office Action alleges that “one of ordinary skill in the art would have found it obvious to rearrange the members to have the self-expanding members be located in the middle portion since it has been held that rearranging parts of an invention involves only routine skill in the art” pursuant to *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Applicants respectfully disagree.

Applicants respectfully point out that *Japikse* is inapposite to the arrangement claimed in claim 79. As noted in the M.P.E.P. § 2144.04(VI)(C), *Japikse* held that “claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were...unpatentable *because shifting the position of the starting switch would not have modified the operation of the device*” (emphasis added). Unlike the starting switches in *Japikse*, rearranging the self-expanding and balloon-expandable members of Vrba would modify the operation of Vrba’s device. Specifically, Vrba at column 2, lines 9-12 describes that Vrba’s configuration provides for the ends to self expand to aid placement after which a balloon may be used to expand the middle portion. Moving self-expanding members into the middle portion as suggested in the Office Action on page 6, as best understood by Applicants, would cause the middle portion of Vrba’s stent to expand at placement, thus operating substantially differently than intended. Thus, Applicants respectfully submit that *Japikse* does not provide a basis for concluding that claim 79 is obvious under 35 U.S.C. § 103 over Kugler, Elliot, Greenberg, and Vrba.

Indeed, Applicants’ recited configuration provides advantages over Vrba’s device. As an example, as noted in Applicants’ specification at paragraph 49, Applicants’ device “may provide for a conveniently self-expanding stent which could be further expanded by a balloon, to attach securely to the wall of the aorta and prevent leakage of blood around the device.” As discussed, Vrba’s device does not function in the same manner. Applicants further note that, even assuming *arguendo* that one with ordinary skill in the art could rearrange the parts of Vrba to produce a device onto which claim 79 would read, “the prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant’s specification, to make the necessary changes in the reference device.” M.P.E.P. § 2144.04(VI)(C). Applicants submit that Vrba (or the other cited art) does not provide the necessary motivation because the references do

not discuss any desire to produce a device that functions as claimed in Applicants' claim 79. Therefore, for at least the foregoing reasons, Applicants submit that claims 74 and 79 are allowable under 35 U.S.C. § 103.

F. Dependent Claims

As discussed above, all pending and new independent claims are allowable over the art of record. Therefore, Applicants respectfully submit that the dependent claims, including the new dependent claims, are allowable at least for depending from an allowable independent claim. While the rejections of the prior-pending dependent claims are thus moot at least for reasons discussed above, Applicants nevertheless submit that the dependent claims recite subject matter not rendered obvious by the art of record.

As an example, claim 61 indirectly depends from independent claim 55 and recites that "the alternating members are configured such that the middle portion is self-expanding to a first diameter and further balloon-expandable to a second diameter, the second diameter being larger than the first diameter." The Office Action on page 6 alleges that "the [section consisting of] balloon expandable members [of Vrba] is fully capable of being expanded to a larger diameter than the [sections consisting of] self-expanding members since the diameter of the balloon expandable members [section] would merely be dependent upon the inflation size of the balloon." Applicants respectfully submit that, even assuming *arguendo* that this were true (Applicants submit that it is not based on Vrba's Figure 6 which appears to show the diameter of the middle section 14 limited by its geometry more than that of the end sections 12), it would be irrelevant to the subject matter of claim 61 which recites that "the middle portion is self-expanding to a first diameter and further balloon-expandable to a second diameter, the second diameter being larger than the first diameter." In other words, claim 61 does not limit the diameter of the middle portion relative to any other portion, but recites that the middle portion is self-expanding to one diameter but further expandable by balloon to another diameter. Vrba does not teach this features as the middle portion 14 of the reference, as acknowledged in the Office Action at page 6, consists of balloon-expandable members. Therefore, Applicants respectfully

submit that claim 61 is allowable under 35 U.S.C. § 103 over Kugler in view of Elliot, Greenberg, and Vrba.

II. Amendment To The Claims

Unless otherwise specified or addressed in the remarks section, amendments to the claims are made for purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof. The amendments are supported by the specification and do not add new matter. In addition, by focusing on specific claims and claim elements in the discussion above, Applicants do not imply that other claim elements are disclosed or suggested by the references. In addition, any characterizations of claims and/or cited art are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by another prosecution. Accordingly, reviewers of this or any child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present disclosure.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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Amdt. dated February 22, 2010
Reply to Office Action of October 20, 2009

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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